NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

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April 3, 2003

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 02N-0276. Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
(68 Federal Register 5377; February 3, 2003)

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits these comments on the proposed rule cited above.

1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5900

The National Food Processors Association (NFPA) is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international Members. NFPA Members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

Summary of Comments

NFPA supports efforts to ensure the security of the food supply, and we endorse and advance activities that can strengthen food security. NFPA and its Members supported the development of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), and worked to perfect its provisions. As the primary representative of the food industry, NFPA shares with FDA an active interest in the implementation of the Bioterrorism

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Act. NFPA commends FDA for its efforts to implement the Bioterrorism Act within a severely limited time frame. The stringent time constraints imposed on this endeavor, however, only increase the importance of cooperation to improve the final rule, by incorporating reasonable and effective recommendations from the regulated industry, including Members of NFPA. NFPA estimates that its Members will be required to register most, if not all, of their facilities.

NFPA's comments on this proposed rule focus on three over-arching principles: First, the need to make the facilities registration process as simple as possible for registrants; second, the importance of ensuring that information collected in the facilities registration process is useful in achieving the stated objectives of the Bioterrorism Act; and, third, the need to limit the scope of registration to those types of facilities clearly envisioned in the statute, to ensure that the registration process does not produce unintended effects.

NFPA has carefully evaluated the implications of the proposed rules. In these comments, when we have concerns about an approach proposed by FDA, we have offered alternative approaches and regulatory language that we believe to be constructive. We ask FDA to consider our comments, realizing that we share the government's goal of protecting the safety and security of the U.S. food supply.

In this rulemaking, FDA does not describe the sources or types of information, from facility registration and other provisions, that the Agency expects to access for responding to an event, or how this information will be integrated or combined to facilitate the Agency's response. FDA does indicate that facility registration information will help Agency and other authorities determine the *source and cause of the event* (emphasis added), and enable FDA to notify quickly the facilities that might be affected. As proposed, the registration requirements are better suited for locating and contacting facilities that through some other means have already been associated with the event, and thus facilitating further investigation, than for determining the source or cause of the event.

With respect to notifying facilities that might be affected by threatened or actual bioterrorism events, the facility registration alone can not offer a sufficiently accurate or effective means to identify a specific subset of facilities to be contacted. In addition, use of FDA product categories will be both inaccurate and ineffective for this purpose. FDA should not attempt to pre-determine which facilities will be potentially affected by a particular event. Such an approach presumes FDA is adequately knowledgeable of the movement of products and ingredients among facilities to make such determinations. NFPA does not believe FDA has, or could possibly obtain, this level of detailed knowledge for the purpose of making large scale, facility-specific notifications. The interest in and need to know about a possible terrorist action against the food industry will be substantial, and FDA should not attempt to isolate potentially affected facilities based on a questionable classification scheme.

Scope of the Registration Provisions, Including Exemptions and Proposed Definitions

FDA Should Adhere to the Intent of the Statute.

FDA should conform closely to the statutory language of the Bioterrorism Act, and, in its spirit, limit the scope of the registration provisions to those that will achieve the objectives of the Act. The provisions of the Bioterrorism Act establish a simple, straightforward registration process. They extend to FDA authority to collect information that would assist the Agency efficiently to investigate events. Since, the registration provisions of the Bioterrorism Act allow for flexibility on the part of FDA, we recommend that the Agency embrace the spirit of the Act and regulate the facilities registration process in as simple a manner as possible, while still creating a process that is effective. In our view, FDA must undertake amendments of the proposed registration regulations to achieve these goals. The proposed rules with respect to scope, exemptions and definitions, as well as required registration information, erode simplicity to the point that exemptions from registration are voided, and would require registrations from a vast array of small facilities. Broadening the scope of the proposal renders invalid FDA's estimates of reporting burden, from the number of affected entities to the time needed to register initially and report future amendments. The potential exists for the registration process to become so unwieldy that it would be difficult for the business sector that is the intended focus of the process, namely, the food industry, to access and update the very database that it recognizes and accepts. NFPA urges that FDA use its discretion to focus the facilities registration rule to achieve most effectively, and without unnecessary burden, the objectives of the Bioterrorism Act.

The Exemption for Fishing Vessels Will Not Achieve its Intended Purpose.

In proposed 21 CFR 1.226(f), regarding the exemption for fishing vessels, FDA reflects the language and reference incorporated into the Bioterrorism Act. Unfortunately, the effect of incorporating the reference to 21 CFR 123.3(k), from the Seafood HACCP rule, into statutory language is to render invalid nearly all of this exemption. Clearly, it is intended to exempt fishing harvest vessels "that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel." Harvested fish must be removed from the harvest vessel for any further processing and introduction into commerce. Only those fishing vessels that transfer harvested fish by brailing or pumping to off-shore processing vessels would be able to benefit from the fishing vessel exemption. Any fishing vessels, including tender vessels, that enter port and off-load fish dockside at any time in their commercial lives would be subject to the facilities registration requirements, because the "dockside unloading" provision eliminates the exemption. This unfortunate consequence is produced by the language of 21 CFR 123.3(k). NFPA requests that FDA

acknowledge the irony of this exemption in the preamble to the facilities registration final rule, and we encourage FDA to consider requesting a technical amendment to the statute in order to secure for the fishing industry the intended exemption for fishing vessels.

Mobile Facilities and Transportation Vehicles Should be Exempt from Registration.

In the Bioterrorism Act, Congress authorized FDA to require registration of "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States." In its selection of types of facilities that would be required to register, Congress clearly envisioned that *stationary* facilities would be subject to registration, noting in the statutory language such facilities as factories, warehouses, and establishments. In short, if Congress had intended for mobile facilities to be registered, Congress would have included transportation vehicles in the scope of the Bioterrorism Act.

In 21 CFR 1.227(c)(2), as proposed, FDA includes a registration requirement for mobile facilities traveling to multiple locations. This requirement would encompass all delivery trucks (including U.S. Postal Service and expedited delivery service vehicles), truck trailers, shipping containers, airplanes, boats, barges, and rail cars that might hold food in transit. The numbers of delivery trucks, truck trailers, shipping containers, airplanes, boats, barges, and rail cars that may transport food for consumption would, in and of themselves, far exceed the number of facilities that FDA estimates would be required to register. Requiring these mobile facilities to register would not help FDA to meet the objective of responding to a bioterrorism threat or incident. When FDA needs to move quickly to identify and locate affected facilities, the mobility of mobile facilities will confound the Agency's best efforts. At any given time, a mobile facility may not be at its registered location, it may contain no food, or it may be empty. The food products in a mobile facility could change constantly, and thus necessitate continuous updates to the mobile facility registration. Large numbers of mobile facilities constantly registering and amending registrations would impede the functioning of the registration system and would provide information of questionable utility. Because of these consequences of requiring registration from mobile facilities, NFPA urges FDA to exclude mobile facilities from the definition of facilities subject to registration.

Research and Development Locations Should be Exempt from Registration.

In 21 CFR 1.227(c)(2), FDA proposes to define "facility" such that research and development (R&D) locations of food companies likely would be subject to registration requirements. R&D facilities typically hold food and often process it on a small scale, but this food is intended for research purposes and not for commercial sale or public consumption. The Bioterrorism Act notes that facilities would be required to register if they manufacture, process, pack or hold food for consumption. Because R&D facilities

appear to be beyond the scope of Congressional intent for registration, they should be exempt from the process. NFPA urges FDA to exclude R&D locations from the definition of "facility" by amending proposed 21 CFR 1.227(c)(2) to include the phrase, "except for establishments engaged in research and development activities" in the first sentence of regulatory text.

Temporary, Small and Secure Holding Locations Should be Excluded from the Definition of "Facility."

FDA's proposed definition of facility also would encompass small and secure but unattended temporary storage locations, such as garages, public storage facilities, and freezer lockers. These small and secure but unattended temporary storage locations generally are 2,000 square feet or less in size. As the Bioterrorism Act addresses broad categories of facilities, but remains silent with respect to size of facility, NFPA believes that FDA has the discretion to exempt these small, temporary and unattended but secure locations from the scope of the registration requirements. These locations may be neither owned nor managed by a facility subject to registration requirements. Their size and inconspicuousness contribute to their security. They are designed to facilitate efficient distribution of food under the control of a processor or distributor. Such locations could not be contacted, as they are unattended and secured. NFPA urges FDA to exclude these small, secure, unattended locations of 2,000 square feet or less from the definition of facility.

Individual Residences Should be Excluded from the Definition of "Facility."

In the same section of proposed rules, FDA has proposed that "Individual homes are not facilities if the food that is manufactured/ processed, packed, or held in the home does not enter commerce." NFPA believes that FDA has not taken into consideration that numerous individuals, such as Girl Scout and Boy Scout volunteer parents, often will hold in their homes cookies or other food products destined for further movement through commerce and ultimate sale to consumers. In addition, volunteers who prepare food in their homes for church bake sales and the like apparently also would be required to register their homes. Residences do not appear to qualify for any proposed exemptions. The Bioterrorism Act does not mention individual residences in the scope of facilities that manufacture, process, pack, or hold food, and we believe that the authors of the Act did not envision that registration requirements would compel ordinary citizens to register their residences. FDA would obtain no useful or actionable information from residence registration, nor would such a requirement be enforceable. NFPA urges that FDA explicitly exempt individual residences, under all circumstances, remove the second sentence of proposed 21 CFR 1.227(c)(2), and include the phrase "except individual residences" in the first sentence of regulatory text.

The Definition of Farms Should be Amended to Ensure that Farms Are Exempt.

In proposed 21 CFR 1.227(c)(3), FDA has imposed conditions that would significantly limit the exemption for farms. This limitation results from the interplay of proposed 21 CFR 1.227(c)(3)(i), the definition of "manufacturing/processing" at proposed 21 CFR 1.227(c)(6), and the definition of "packing" proposed at (c)(8).

In (c)(6), "manufacturing/processing" is proposed to include such activities as cutting, trimming, and washing that are part of traditional farming activities performed during or immediately after harvest of nearly all farmed commodities. Examples of these activities include threshing of grain (cutting), and potable water washing and cosmetic trimming of harvested fruits and vegetables. Such activities also may include boxing of produce or enclosing farm products in protective wrappers, which appears to meet the definition of "packing" proposed in (c)(8). In order to ensure that farms maintain the exemption that was intended under the statute, NFPA urges FDA to amend 21 CFR 1.227(c)(3)(i) as follows (suggested addition underscored):

(3) Farm means a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both. The term "farm" includes:

(i) Facilities that <u>cut, trim, or wash food in operations integral to harvest, or</u> pack, or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm,

FDA should also clarify that the exemption for farms is also applicable to foreign farms.

Food Other Than for Consumption Should be Exempt from Registration.

In proposed 21 CFR 1.227(c)(4), the definition of food extends beyond the concept of "food for consumption" articulated in the statute. The proposal overlooks the statutory focus on facilities involved with food <u>for consumption</u> and includes facilities that do not make or hold food *for consumption,* such as food contact packaging and components, food contact equipment, indirect food additives. Including food contact packaging and components will create an unnecessary administrative burden for industry and FDA, and will result in the collection of data that has limited utility in achieving the objectives of the Bioterrorism Act. FDA should exempt these facilities from registration requirements.

"Trade Names" Should be Defined.

In the Bioterrorism Act, it is specified that registration information must include all trade names under which a registrant conducts business. "Trade names" are terms of art as used in the statute and the proposed rule, and are referenced several times yet are not defined. It is necessary to encode such a definition, to ensure that the scope of registration reflects the intent and objectives of the statute. As used in the food industry, "trade names" signify terms related to a business enterprise, rather than terms associated with individual products. "Trade names" signify the names under which the facility conducts business, or other names by which the facility is known, including the division or subsidiary of a larger corporation by which the facility is known. FDA has captured this correct meaning in the instructions on the proposed paper registration form. FDA should reflect this meaning in the definitions for the registration proposal. In addition, FDA should clarify in the preamble to the final rule that the definition of "trade names" denotes terminology associated with the business of the facility, and does not necessarily signify a brand name, which is terminology associated with a product. FDA should also provide clear examples to illustrate the concept of "trade names," such as: Facility name: Jones Foods Corporation; Trade Names: doing business as Joe Jones Fruit Processors, doing business as Jones Family Pie Company. To reflect these meanings, NFPA urges FDA to and include a new paragraph in the definitions of 21 CFR 1.227(c) that states:

"Trade names" mean the terms relating to the business activity of the facility that denote the names under which the facility conducts business or additional names by which the facility is known.

Definition of U.S. Agent Should be Clarified.

In proposed 1.227(c)(5), FDA puts forward a definition for U.S. agent. In this definition, FDA should clarify that the term "person" includes an individual, partnership, corporation, and association, the stated meaning of the term in section 201(e) of the Federal Food, Drug, and Cosmetic Act, and does not necessarily imply that this term only means a specific individual.

Procedure for Registration

Electronic Registration System Must be Simple and Efficient.

In proposed 1.231(a), FDA puts forward a process for electronic registration. NFPA urges FDA to ensure that the operation of this electronic registration system is designed to accommodate the anticipated high level of activity.

No opportunity was provided to review the electronic data collection system, and the design of the paper registration form does not allow for analysis of the electronic data entry system. The lack of a clear illustration of the electronic facility registration system

makes it impossible to determine whether it will operate quickly and efficiently, to minimize the burden on registrants. NFPA imagines that the electronic registration system would parallel the paper system. Since FDA envisions the electronic data collection to be an integral part of the facility registration provision, NFPA believes that this lack of opportunity to review and analyze the electronic registration system is an unfortunate shortcoming. Many facilities will be required to register in an eight week time period, and any flaws in the electronic registration system will cause serious disruptions to commerce and trade, as well as impede the industry's ability to comply with facility registration.

There are many electronic data entry systems that might be built around the architecture of FDA's proposed reporting form; some systems could be quick and easy to use and some could be difficult and time consuming, but both could legitimately reflect the facility registration reporting form. NFPA urges FDA to ensure that the mechanics of electronic facility registration are simple and minimize the reporting burden.

Registration Data Must be Secure.

Reviewing the proposed paper registration form does not reveal any provision for data security for original data entry and subsequent changes for the electronic data collection system. NFPA members have concerns about the security of the electronic registration system and safeguards to ensure that their company data will not be compromised. It appears that a registration number alone would be sufficient to access the facility registration data in an electronic environment. This mode of access is not sufficiently secure. Registration numbers, when available, will be required for prior notice of imports, and are likely to become part of the commercial documentation between parties buying and selling food products. NFPA strongly urges FDA to add other data security measures, such as secure passwords, to the electronic registration system. FDA must take measures to ensure that registrant data are not vulnerable in the electronic registration system. FDA must have procedures in place to ensure that only authorized persons can access and change their facility's registration information.

Multi-Facility Registration Must be Facilitated.

FDA can improve the process of electronic registration if multi-facility registrants were able to send a single transmission containing all of the required data, in lieu of entering the data interactively over the Internet. The interactive Internet data entry approach may be suitable for many small firms, but is too time consuming for companies that must register hundreds, if not thousands, of facilities. Based on an estimate of one hour to complete a registration entry, companies with 1,000 regulated facilities could need 1,000 person hours, or half a person year, to enter data for their facilities. It would take several full-time administrative personnel working 40 hours per week to complete such a task in

the eight weeks that will be provided for compliance with the registration process. Thus, we strongly suggest that the final rule include an option for a format for submitting electronic data files, such as XML documents, Microsoft Excel documents, or standard flat files. NFPA proposes the following amendments to proposed 21 CFR 1.231:

(a) Electronic registration: To register electronically, you must register at [a Web site that will be provided in the final rule], which will be available for registration 24 hours a day, 7 days a week, unless you follow the data transfer procedure specified in paragraph (a)(1). This Web site will be available wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes, as well as a foreign facility's U.S. agent if the facility makes such arrangements. FDA strongly encourages electronic registration for the benefit of both FDA and the registrant. Once you complete your registration, FDA will provide you with an automatic electronic confirmation of registration and a permanent registration number. You will be considered registered once FDA electronically transmits your confirmation and registration number unless notified otherwise.

(1) Companies registering multiple facilities may also prepare an electronic registration for their facilities by which the required information may be transmitted in batch form to FDA. FDA will provide automatic electronic confirmation of registration and permanent registration numbers for facilities registered by this method.

NFPA also recommends that FDA allow a single registrant entering data for many facilities to stop entering data on one day and renew the task again another day, beginning from the previous data entry point achieved, for interactive data entry, and allow for the simultaneous data entry for a multi-facility registrant from multiple computer stations. FDA should allow for multiple electronic registration techniques to ensure that the facility registration system is sufficiently flexible to meet the needs of the wide range of registrants.

Required Registration Information

The Bioterrorism Act specifies that registration information is required to include information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business. NFPA urges FDA to adhere to this simple statutory scheme, which clearly envisions that only a few data points should be required for registration. No other registration information should be required. NFPA concedes that a facility telephone number is a valid datum related to address, as telephone numbers and physical locations are correlated in telephone directories, but that other information is superfluous and should not be required.

Emergency Contact Information System Should be Modified.

In 21 CFR 1.232(c), FDA proposes to require emergency contact information in the facility registration. NFPA recommends that FDA amend its approach to this section of registration information, to ensure that the emergency contact system permits rapid contact with registrants, while allowing needed flexibility that addresses the needs of various types of registrants. Given the wide range of company types and sizes that will be subject to registration, FDA should encourage individual companies to determine how they should be integrated into the Agency's emergency contact structure.

NFPA agrees that having a means to contact a facility quickly and efficiently will greatly facilitate FDA's functions and will meet the objectives outlined in the Bioterrorism Act. However, the proposed emergency contact information, which is individual-specific, offers limited utility in some circumstances. There is no guarantee that an individual emergency contact will be at the office or at home at the precise time of an emergency. Many food facilities are round-the clock-operations, with the initial point of contact being a security person that engages in shift work. The facility's main telephone number may or may not be staffed 24 hours a day. It is not necessary for FDA to know the name or title of the individual who may answer the telephone, or even to ask for a specific individual by name. FDA could easily indicate it is attempting to initiate an emergency contact. The only information that FDA needs is that which will provide the Agency a point of contact for someone responsible for an emergency situation at a facility at any hour. Individual registrants would be sufficiently familiar with their own emergency procedures that they can provide whatever information will facilitate that point of contact.

NFPA recommends that FDA encourage food facilities to develop emergency procedures that would be triggered by a contact from an FDA representative in an identified emergency. Many companies have procedures and operational structures to facilitate expeditious handling of emergencies on a 24-hour basis. It must be noted that FDA is not the first public agency to interface with a food company's emergency system; food facilities often provide generic emergency contact information to law enforcement, fire, and rescue agencies in their communities. These emergency systems function well without a specific individual necessarily being named. Individual companies should be free to determine how emergency contact operations best fit their structure. Any given facility or parent company taking responsibility for an emergency contact system should not be bound by the specific information required in FDA's proposed reporting framework. NFPA believes that facilities or their parent companies should be given the option of identifying relevant emergency contact information (phone number – cell or land line; email) without necessarily identifying a specific individual. NFPA also notes that identifying personal information is likely to change often, with personnel changes, thus necessitating frequent updates to the information.

Product Code Information Should Not be Required.

In proposed 21 CFR 1.232(e), FDA would require information on product categories as identified in 21 CFR 170.3. NFPA believes that this information should not be required for facility registration purposes. NFPA believes that FDA has not sufficiently justified the requirement for this information, and thus should not require it.

The Bioterrorism Act gives FDA discretion to gather general food category data, but the law does not mandate collection of such information. The general food categories identified under 21 CFR 170.3 are to be used, if FDA determines through guidance that product category information for each facility is necessary. FDA has correctly acknowledged the problems associated with use of the outdated categories in 21 CFR 170.3, which were designed for applications regarding the regulation of food additive uses, and thus are not relevant for the facility registration information collection. Nevertheless, the Agency has tentatively decided to require submission of FDA product code categories, referencing the 21 CFR 170.3 categories, erroneously concluding, in our view, that tracking FDA product code categories

> "is necessary for a quick, accurate, and focused response to a bioterrorism incident or other food-related emergency, because the categories will assist FDA in conducting investigations and surveillance operations in response to such an incident. These categories will also enable FDA to quickly alert facilities potentially affected by such an incident if FDA receives information indicating the type of food affected." 68 FR 5384.

The product code information will not ensure rapid contact with a registered facility in the event of an actual or threatened bioterrorism event, and collecting information about the categories associated with each facility would not be useful in reducing threats to the food supply. Use of the proposed general product categories for identifying potentially affected facilities introduces huge uncertainties as to whether the appropriate facilities would be contacted or not, which may either lead to causing unnecessary concern or inadequate notification of facilities. The proposed product categories only add to the reporting burden of registrants.

Classifications Using FDA's Product Codes are not Self-Evident.

As a practical matter, the FDA product categories are difficult to understand and apply, even for specialists who deal with these sections of regulations daily. In order to assign an individual food item to a category, one must become familiar with FDA's encoding system. A firm must take the time and spend the money to determine the accurate FDA product code for each product formulation that the company makes, and then, from that

detail, determine the FDA product code category. Some categories overlap each other, yet many foods fall into gaps among the categories; so, deciding which category FDA would deem correct can be quite difficult. Many food processors are likely to classify similar products differently or make mistakes in reporting category classification. Inconsistency and errors could lead to a database full of useless information. In short, the FDA product code categories are simply no more useful in fostering the Agency's mission of maintaining the safety of the food supply than would be the 21 CFR 170.3 categories FDA properly rejected. Any product categorization would need to be self-evident, and any technique for determining a product category should be transparent to the registrant.

FDA's Product Codes Provide a Questionable Basis for Notifying Facilities.

It is important to recognize that one food processor's product is another's ingredient. Many of the proposed FDA categories are for foods that are virtually ubiquitous throughout the food supply, like cheese, dried milk products, flours, and vegetable oils, and nearly all the product categories are used as ingredients in further processed foods. FDA's anticipated use of product codes for "targeted communication" would address only primary ingredient manufacturers, not processors throughout the system that use those ingredients in other food products. Improperly targeted communication based upon the FDA product code categories would hinder, rather than foster, effective response to a potential threat as well as the associated FDA investigations and surveillance operations.

In summary, collection of FDA product code category data is not required by the Bioterrorism Act, is unnecessary for the accomplishment of FDA's mission, and is not useful as a practical matter. Tracking FDA product codes for each facility would increase the cost of the registration system and divert resources that should be focused elsewhere, but would not improve the Agency's capacity to protect the public. Consequently, NFPA urges FDA to eliminate the requirement for product code category information.

The Certification Process for Registration Information Needs to be Clarified.

In proposed 21 CFR 1.232(g), FDA outlines the requirements for the certification of registration information:

"A statement certifying that the information submitted is true and accurate, and that the person submitting the registration is authorized by the facility to register on its behalf. The statement requires the name of the person registering the facility. This statement also requires the phone number, e-mail address (if available), and fax number (if available) of the person submitting the registration."

NFPA notes that the requirements for identifying personal information should relate to the individual making the certification, not necessarily the individual making the registration, recognizing that administrative personnel, not responsible parties of the company or the facility, may process the actual facility registration.

Summary of Recommended Registration Data Elements that Should be Required.

To summarize and reflect the modifications to required registration information that we have discussed above, NFPA urges FDA to amend proposed 21 CFR 1.232 as follows (text additions are underscored, text deletions are stricken through):

Sec. 1.232 What information is required in the registration?

Each registrant must submit the following information through either of the methods described in Sec. 1.231:

(a) The name, full address, and phone number~~, fax number, and e-mail address~~ of the facility;

(b) The name and address of the parent company, if the facility is a subsidiary of the parent company;

(c) Emergency contact ~~information,~~ telephone number for initiating a contact 24 hours a day; ~~an individual's name, title, office phone, home phone, cell phone (if available), and e-mail address (if available)~~;

(d) All trade names the facility uses;

~~(e) Product categories as identified in Sec. 170.3 of this chapter;~~

(f) For a foreign facility, the name, address, and phone number, ~~fax number (if available), and e-mail address (if available)~~ of its U.S. agent;

(g) A statement certifying that the information submitted is true and accurate, and that the person ~~submitting~~ certifying the registration information is authorized by the facility to ~~register~~ confirm the information on its behalf. The statement requires the name and telephone number of the person ~~registering the facility~~ making the certification. ~~This statement also requires the phone number, e-mail address (if available), and fax number (if available) of the person submitting the registration.~~

Updating Registration Information

The Bioterrorism Act specifies that changes to registration information must be made in a "timely manner," but is silent as to what time frame meets that condition. NFPA believes that FDA has sufficient discretion to establish the appropriate meaning of timeliness. In proposed 21 CFR 1.234, FDA outlines the procedure for updating registration information, specifying that any change in information must be reported to FDA within 30 days. As proposed, the need for updating registration information is triggered by any change in the facts. Some data elements are likely to change frequently. The reporting burden can be reduced if FDA were to amend its proposed requirements to reflect that changes may be made within a 180-day time frame. The longer the period permitted for changes, the less the reporting burden on respondents, with little or no degradation in timeliness of information. Critical information in the registration, such as the facility location, is not likely to change, and six months is a sufficient time frame to notify FDA of changes in non-critical required information. Furthermore, FDA should establish no time frame for requiring updates to any optional information in the registration. NFPA urges FDA to adopt a system so that registration information need not be updated within 30 days, and allow for updates every six months. As with initial electronic registration, changes to reported information must be simple to execute.

FDA Should Provide a Special Procedure for Changes in Facility Ownership.

NFPA urges that FDA provide a procedure related to change in ownership or management of a facility. A registered facility should be able to keep its registration number through change in ownership or management. At some point in the process of ownership or management change, the former registrant would no longer be authorized to make a change, and certainly could not represent the information of the new owner.

Responsibility for Bonded Hold if Foreign Facilities Fail to Register Must be Clarified.

In proposed 1.241(f) , FDA outlines the procedure in the event foreign facilities fail to register, and who is responsible for moving product into bonded hold. The parties designated by FDA as responsible may have had nothing to do with the failure of the foreign facility to register. FDA should clarify that any party of the commercial import process, including the shipper, could be responsible for arranging the bonded hold. FDA needs simply to clarify that such arrangements are not the responsibility of FDA.

Any Revocation of Registration is Inconsistent with the Bioterrorism Act.

FDA requested comment on circumstances under which a firm's registration should be considered null and void, and on circumstances under which a firm's registration should

be revoked. FDA also requested comment on the process for such determinations (68 FR 5386).

The Rule of Construction in the Bioterrorism Act notes that "nothing in this section shall be construed to authorize the Secretary to require an application, review, or licensing process." Thus, the statute envisions registration as a process by which FDA is prohibited from any activity that might appear to be an approval. If approval may not be extended, it also may not be withdrawn. The Rule of Construction suggests that FDA generally may not render a registration null and void, nor revoke a registration. NFPA suggests that if a registration is made fraudulently, and thus in contravention of the certification, only then should FDA be permitted to vacate a registration. NFPA suggests that the ordinary criminal process to prove fraud should be available to FDA for this purpose.

Conclusion

The Bioterrorism Act established a minimal, straightforward registration procedure that could help FDA to locate and contact food facilities in a timely way. As proposed, FDA's registration regulations would unduly complicate a nationwide food facility registration process and database. By going beyond what is called for in the Bioterrorism Act, FDA is proposing a system that will be largely unenforceable and would impose costs on industry that will yield limited benefits. NFPA's intent with these comments has been to suggest ways for FDA to improve the effectiveness and efficiency of the facility registration system and better serve our shared goal of protecting the U.S. food supply.

Thank you for the opportunity to comment on this important issue. We stand ready to assist FDA in perfecting this rule.

Sincerely,

Rhona S. Applebaum, Ph. D.
Executive Vice President and
Chief Science Officer